

### REMARKS

This Amendment filed in response to the Office Action dated June 30, 2004, accompanied by an extension of time for two additional month is timely filed within the five month time period for response, which time period is set to expire on November 30, 2004. Reconsideration of this application is requested in view of the foregoing amendments and the following remarks.

Before this amendment, claims 1, 2, 4-7 and 11-14 were under consideration. Claims 1, 7 and 12 have been amended in this amendment. Claims 1, 2, 4-7 and 11-14 are still pending for consideration. Support for the amendment to claims 1 and 12 is found in the specification on page 8, line 8 to page 8, line 13. Claim 7 amendment corrects formalities. Thus, no new matter has been added by these amendments.

### Drawings

The drawings were objected to under 37 C.F.R. 1.83(a). Applicants have amended the drawings consistent with the description of the specification and believe that this objection is now moot. New reference numeral 9 is added. No new matter is added by this amendment.

### Claim Objections

Claims 1-2, 4-7, 11 were objected to because of certain informalities. Applicants have amended the specification and claims in response to this objection. Accordingly, this objection is now moot.

### Claim Rejections – 35 U.S.C. §102

Claims 1-2, 4-7, 11-14 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,378,475 (Smith) or U.S. Patent No. 6,001,386 (Ashton). Applicants respectfully traverses this rejection.

Claim 1 sets forth a sustained release drug delivery device comprising a drug core. The drug core has at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. The drug delivery device also has an impermeable coating layer that is impermeable to the passage of the agent. The impermeable coating layer is adjacent to the drug core that surrounds a portion of the drug core.

A suture tab is adhered to and extends from the drug delivery device. The suture tab is used during surgery to adhere the device to the body of a mammalian organism. The drug delivery device includes a permeable polymer coating layer that is permeable to the passage of the agent. The permeable polymer coating layer essentially completely covers the impermeable coating layer and the uncoated portion of the drug core that is not coated with the impermeable coating layer. The permeable polymer coating layer is of a similar polymer material as the suture tab and both polymer coating layer and suture tab have been cured at the same time, bonding both together.

Claims 2, 4-7 and 11 depend from claim 1 and contain all of the elements thereof.

Claim 12 covers a method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect. The method comprises inserting in a desired location in the body of a mammalian organism a sustained release drug delivery device. The sustained release delivery device comprises a drug core with at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. A impermeable coating layer that is impermeable to the passage of the agent is adjacent to and surrounds a portion of the drug core. A suture tab is adhered to and extends from the drug delivery device and is used during surgery to adhere the device to the body of a mammalian organism. A permeable polymer coating layer that is permeable to the passage of the agent essentially completely covers the impermeable coating layer and the uncoated portion of the drug core that is not coated with the impermeable coating layer. The permeable polymer coating layer is of a similar polymer material as the suture tab. Both polymer coating layer and suture tab have been cured at the same time thereby bonding both together. Claims 13-14 depend from claim 12 and contain all of the elements thereof.

The present invention is different from one or more of the prior art references because it has an impermeable polymer coating that is adjacent the drug core. Likewise, the present invention is different from one or more of the prior art references because it has a permeable polymer coating with a suture tab that is made of the same material as the permeable polymer coating and are cured at the same time—binding both together. The process of curing the permeable polymer coating and the suture tab at the same time results in a device that is

considerably stronger than prior art suture tabs.

Smith does not teach an impermeable coating that is adjacent to the drug core or reservoir. The drug core in Smith is surrounded by a permeable polymer coating 15. See Smith column 4, lines 39-45. Additionally, Smith does not teach how to attach the suture tab. The suture tab appears from the drawing to be a separate item. Thus, Smith does not anticipate claim 1 as well as claims 2, 4-7 and 11, which claims depend upon claim 1. Likewise, Smith does not anticipate claim 12 as well as claims 13-14 which depend from claim 12.

Ashton does not anticipate claims 1-2, 4-7 and 11-14. Ashton does not teach attaching a permeable polymer coating to a suture tab that is made of the same material as the permeable polymer coating and are cured at the same time—binding both together. The process of curing the permeable polymer coating and the suture tab at the same time results in a device that is considerably stronger than prior art suture tabs and obviates the needs for reinforcement.

Ashton teaches the manufacture of a suture tab as follows: “ Some pellets were then coated in PVA and heated to 120°C and trimmed leaving a suture tab attached....” See Ashton col. 7, lines 59-61. To make the device sufficiently strong, a support ring or backing was embedded in the permeable polymer coating. See Ashton col. 7, lines 59-61. However, adding a backing material adds additional parts to the device and additional assembly steps. Thus, the device of the present invention is sufficiently strong without the need for a support ring or backing. Ashton does not anticipate independent claims 1 and 12 as well as dependent claims 2, 4-7, 11, and 13-14 which depend upon one of claims 1 and 12.

Claims 1-2, 4-7, 11-14 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,713,081 (Robinson) or U.S. Patent No. 6,413,540 (Yaacobi) or U.S. Patent No. 5,902,598 (Chen).

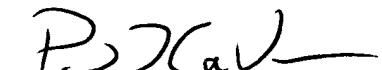
Robinson does not teach an impermeable coating that is adjacent to the drug core or reservoir. Robinson teaches a dual mode drug delivery device. The first mode is a composite matrix material. The second mode is a drug tablet that is inside the composite matrix material. The composite matrix material is permeable to the therapeutic agent. Thus, Robinson does not teach an impermeable coating that is adjacent to the drug. Robinson does not anticipate independent claims 1 and 12 as well as dependent claims 2, 4-7, 11, and 13-14 which depend upon one of claims 1 and 12.

Yaacobi does not teach an impermeable coating that is adjacent to the drug core or reservoir. Yaacobi does not teach a permeable polymer coating layer that essentially completely covers the impermeable coating layer and the uncoated portion of the drug core that is not coated with the impermeable coating layer. Yaacobi teaches a body having an inner core comprising a pharmaceutically active agent disposed in a well. As a result, Yaacobi does not anticipate independent claims 1 and 12 as well as dependent claims 2, 4-7, 11 and 13-14 which depend upon one of claims 1 and 12.

Chen (like Smith) does not teach an impermeable coating that is adjacent to the drug core or reservoir. The drug core in Chen is surrounded by a permeable polymer coating. See reference 10 in Fig. 1. Additionally, Chen does not teach how to attach the suture tab or of what the suture tab is made. The suture tab appears from the drawing to be a separate item that is imbedded in the third coating. Thus, Chen does not anticipate independent claims 1 and 12 as well as claims 2, 4 –7, 11, and 13-14, which claims depend upon one of claims 1 and 12.

Applicants believe that the application is in condition for allowance. An early and favorable action on the merits is solicited.

Respectfully submitted,

  
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## **AMENDMENTS TO THE DRAWINGS**

The attached substitute sheet of drawings includes changes to Figs. 1 and 2. This substitute sheet, which includes Figs. 1-2, replaces the original sheet including Figs. 1-2. Also attached is an Annotated Sheet Showing Changes circled in red and highlighted in yellow.

In Figs. 1-2, the impermeable coating layer and reference numeral 9 was added. Support for this amendment was found on page 8, fourth complete paragraph. No new matter has been added by this amendment.



Figure 1

